CTMS Structured Protocol Representation SIG Teleconference Meeting Notes

Meeting Date	Tuesday, September 7, 2004 1-2 PM EDT
Attendees:	**Working group coordinator**: Scott Finley (Booz Allen Hamilton) Harshawardhan Bal (Booz Allen Hamilton) **Participants:**

Name	Email	Center
Doug Fridsma (SIG lead)	fridsma@cbmi.pitt.edu	UPMC
Hemant Shah	hshah@coh.org	City of Hope
Sharon Elcombe	elcombe@mayo.edu	Mayo
Christo Andonyadis	andonyac@mail.nih.gov	NCI
Smita Hastak	hastaks@mail.nih.gov	NCI
Andrea Hwang	ychwang@uci.edu	UC Irvine
Joyce Niland	jniland@coh.org	City of Hope
Lakshmi Grama	lgrama@mail.nih.gov	Cancer Information Products and Systems, NIH
Robert Morrell	bmorrell@wfubmc.edu	Wake Forest CCC
Beverly Meadows	meadowsb@ctep.nci.nih.gov	CTEP
Marsha Ketcham	mketcham@unmc.edu	University of Nebraska Medical Center
Oleg Shats	oshats@unmc.edu	University of Nebraska Medical Center
Linda Schmandt	lschmandt@cbmi.pitt.edu	UPMC

Agenda	---
General discussion points raised by participants:	A highly federated development team that would work in close collaboration was suggested as a possible framework for creating the Protocol authoring tool. Any dependencies between adopters and working group participants and the developers (UPMC) would need to be worked out at an early stage of the development process. Requirements that were simple and controlled by NCI could be targeted for the early development. One approach would be to start with Summary 3 (Reportable patients/accrual to therapeutic protocols) and 4 (Clinical Research Protocol Information) documents, understand the data elements and reporting requirements and work back to the protocol representation and

	the needed tools. Simultaneously information such as common unique protocol Ids, disease sites to cover, what data should be reported, etc., needs to be defined. The Protocol authoring tool could be built iteratively and future needs identified as the development proceeds and added at the appropriate stage. As the iterations progress, the underlying infrastructure (for example, the database) may become stable and only the rules may need to be changed. Data could then be aggregated based on an existing set of rules. Since NCI has changed Summary 4 several times previously, reporting requirements may change and may need to be updated periodically. The Protocol authoring tool may use the current way of reporting and incorporate changes incrementally as necessary. Participation from other relevant groups - cooperative groups, Pharma, Eastern Cooperative Oncology Group (ECOG), and others – was considered important to enable the development of a comprehensive set of use cases that covered the needs of both academia and industry. Since different centers have different reporting formats, it would be useful to harmonize the reports to a standard consistent format. Possible agenda items for the November CTMS face-to-face meeting at City of Hope were discussed. Joyce Niland suggested sessions devoted to gathering use cases for the adverse events module and for Summary 4 document.
Action items:	• Coordinate with Joyce Niland and Andrea Hwang for deriving use cases based on the NCI Summary 4 document • Obtain list of individuals from cooperative groups and Pharma companies (from Becky Cush, CDISC) for Protocol authoring tool user requirements gathering • Send suggestions for agenda items to Scott Finley for the November CTMS face-to-face meeting at City of Hope • Work with Bob Morrell to create a white paper on Summary 3 and 4